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LABORATORY REPORT

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REPORT

TEST FACILITY

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STUDY TITLE

Cytotoxicity Study Using the ISO Agarose Overlay Method (Solid)

TEST ARTICLE NAME

Repellix Coating

TEST ARTICLE IDENTIFICATION

Not Supplied

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Summary

An *in vitro* biocompatibility study, based on the requirements of the International Organization for Standardization (ISO 10993-5), was conducted on the test article, Repellix Coating, to determine the potential for cytotoxicity. Triplicate wells were dosed with a 1 cm x 1 cm portion of the test article. Triplicate wells were dosed with a 1 cm length of high density polyethylene as a negative control. Triplicate wells were dosed with a 1 cm x 1 cm portion of latex, as a positive control. Each was placed on an agarose surface directly overlaying a subconfluent monolayer of L-929 mouse fibroblast cells. After incubating at 37°C in 5% CO_2 for 24 hours, the cell culture was examined macroscopically for cell decolorization around the test article and controls to determine the zone of cell lysis (if any). The culture was then examined microscopically (100X) to verify any decolorized zones and to determine cell morphology in proximity to the articles.

Under the conditions of this study, the test article showed no evidence of causing cell lysis or toxicity. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity). The negative control and the positive control performed as anticipated.

Study and Supervisory Personnel:

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7.29.08
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For the suitability of the system to be confirmed, the negative control must have been a grade of 0 (reactivity none) and the positive control must have produced a zone of lysis (reactivity moderate to severe). The test article passed the test if all three monolayers exposed to the test article showed no greater than a grade of 2 (reactivity mild). The test would have been repeated if the controls did not perform as anticipated and/or if the test wells did not yield the same conclusion (e.g., one well passed and the other two wells failed).

5. Results

The scores obtained were as follows:

ARTICLES		ZONE OF LYSIS (mm)	GRADE	REACTIVITY
Test Article:	(1)	0	0	none
	(2)	0	0	none
	(3)	0	0	none
Negative Control:	(1)	0	0	none
	(2)	0	0	none
	(3)	0	0	none
Positive Control:	(1)	12	4	severe
	(2)	12	4	severe
	(3)	12	4	severe

6. Conclusion

Under the conditions of this study, the test article showed no evidence of causing cell lysis or toxicity. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity). The negative control and the positive control performed as anticipated.

Results and conclusions apply only to the test article tested. Any extrapolation of these data to other samples is the sponsor's responsibility. All procedures were conducted in conformance with good manufacturing practices and certified to ISO 13485:2003.

7. Records

All raw data pertaining to this study and a copy of the final report are to be retained in designated NAMSA archive files.

8. References

International Organization for Standardization (ISO) 10993-5. Biological Evaluation of Medical Devices - Part 5: Tests for Cytotoxicity, *In Vitro* Methods (1999).

United States Pharmacopeia 30, National Formulary 25 (USP), General Chapter <87>, Biological Reactivity Tests, In Vitro (2007).

Wilsnack, R. E., F. J. Meyer and J. G. Smith, "Human Cell Culture Toxicity Testing of Medical Devices and Correlation to Animal Tests," *Biomaterials, Medical Devices and Artificial Organs* 1 (1973): 543-562.